UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,627	04/12/2004	Jianbo Xie	141-400	3299

47888 7590 09/17/2007

HEDMAN & COSTIGAN P.C.
1185 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER	
KARPINSKI, LUKE E	
ART UNIT	**PAPER NUMBER**
1609	

MAIL DATE	DELIVERY MODE
09/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/822,627	XIE ET AL.	
	Examiner	Art Unit	
	Luke E. Karpinski	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2 pages*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election Requirement

Applicant's election filed on 8/20/2007 is acknowledged. In regards to Species IV (a plasticizer), the applicant's arguments were persuasive and the election requirement has been withdrawn. However, the arguments for withdrawal of the species requirement for Species I-III were not persuasive, the species election requirements for species I-III are proper and still stand. The compounds found within Species II belong to several different groups; have different structures as well as different reactivities. The compounds found within species II-III have different structures and thus will also have different reactivities. Therefore the species election requirement for species IV has been removed but the species election requirement for species I-III still stands.

Objection

Claim 7 is objected to because of the following informalities: The word "osmopolymer" is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,478,577 to Sackler in further view of US Patent No. 6,372,255 to Saslawski.

3. Sackler teaches a sustained release oral pharmaceutical (title) comprising:

(a) a core (col. 7, lines 60-63; the invention having a coating must have a core to be coated) comprising:

(i) an opioid analgesic (col. 7, lines 31-34);

(ii) at least one pharmaceutical excipient (col. 12, lines 45-50)

(b) a delayed release coating surrounding the core (col. 7, lines 60-63) comprising:

(i) a first enteric coating agent (col. 8, lines 15-19)

(ii) a second enteric coating agent (col.13, lines18-21)

(iii) optionally a plasticizer (col. 9, lines 31-33)

(iv) optionally an inert processing aid (col. 8, lines 10-12) and

(c) an immediate release drug layer (col. 6, lines 25-60) comprising;

(i) an opioid analgesic (col. 6, lines 25-27

(d) optionally a cosmetic coating (col. 7, lines 63-67)

4. Sackler does not teach a binder found within the immediate release drug layer. However, Saslawski does teach a binder found within the immediate release drug layer (col. 5, line 59-col. 6, line13). Saslawski directly relates to the art, in that it teaches a tablet for instant and prolonged release of one or more active substances. It would have been obvious at the time of the invention for one of ordinary skill in the art to combine Sackler and Saslawski to add a binder, which is common in the art, to an immediate release drug layer.

5. In regards to claims 2 and 3: Sackler teaches oxycodone (col. 7, lines 31-32).

6. In regards to claims 4-7: Sackler teaches several different excipients and combinations thereof (col. 12, lines 45-50). Sackler also teaches that the core may contain binders (col. 12, lines 45-50) and that said binder may be an osmopolymer (col. 12, lines 7-8)

7. In regards to claim 8 and 9: It is assumed that the binders named in Saslawski have a viscosity of greater than 50,000 mPa. It is also noted that binders are common in the art and that all binders act as functional equivalents for this invention, it is also noted that any nominal change in viscosity properties of said binders should not change the scope of this invention and therefore it is sufficient to reject this claim based on the rejection of a binder in the broader sense.

8. In regards to claims 10-12: It is assumed that the first enteric coating and the second enteric coating agent elected by the Applicant meet the limitations of claims 10-12 and therefore claims 10-12 are rejected over the basis that methacrylic acid polymer begins to dissolve around a pH of 5-7 and that zein begins to dissolve at a pH of about 8-12. It is further noted that the phrase "begins to dissolve" is relative, in that, any enteric polymer will "begin" to dissolve when contacted with a solution at any pH value.

9. In regards to claims 13-16: Changing the percentages as well as the ratios of components in pharmaceutical compositions is common in the art and is simply seen as routine optimization in the art.

10. In regards to claim 17: Sackler teaches a sustained release oral pharmaceutical (title) comprising:

(a) a core (col. 7, lines 60-63; the invention having a coating must have a core to be coated) comprising:

(i) an opioid analgesic (col. 7, lines 31-34);

(ii) a diluent (col. 12, lines 47);

(iii) a binder (col. 12, lines 47); and

(b) a delayed release coating surrounding the core (col. 7, lines 60-63) comprising:

(i) a first enteric coating agent that is assumed to begin to dissolve at a pH of about 5-6 (col. 8, lines 15-19);

(ii) a second enteric coating agent that is assumed to begin to dissolve at a pH of above 8 (col.13, lines18-21);

(iii) an inert processing aid (col. 8, lines 10-12);

(iv) optionally a plasticizer (col. 9, lines 31-33); and

(c) an immediate release drug layer (col. 6, lines 25-60) comprising;

(i) an opioid analgesic (col. 6, lines 25-27

(d) optionally a cosmetic coating (col. 7, lines 63-67)

11. Sackler does not teach a binder with the viscosity disclosed in the instant application in claim 17. Saslawski does teach binders used in the same art in immediate release coatings with a viscosity that is assumed to be greater than 50,000 mPa when at the conditions given in claim 17 of the instant application. It is also noted that for the purpose of the instant application any binder should achieve the desires effect.

12. Sackler also does not teach an immediate release drug layer comprising a binder. Saslawski does teach a binder found within the immediate release drug layer (col. 5, line 59-col. 6, line13). Saslawski directly relates to the art, in that it teaches a tablet for instant and prolonged release of one or more active substances. It would have been obvious at the time of the invention for one of ordinary skill in the art to combine Sackler and Saslawski to add a binder, which is common in the art, to an immediate release drug layer.

13. In regards to claims 18 and 19: Sackler teaches oxycodone (col. 7, lines 31-32).

14. In regards to claim 20: It is assumed that the binders named in Saslawski have a viscosity of greater than 50,000 mPa. It is also noted that binders are common in the art and that all binders act as functional equivalents for this invention, it is also noted that any nominal change in viscosity properties of said binders should not change the scope of this invention and therefore it is sufficient to reject this claim based on the rejection of a binder in the broader sense.

15. In regards to claims 21-22: It is assumed that the first enteric coating and the second enteric coating agent elected by the Applicant meet the limitations of claims 21-22 and therefore claims 21-22 are rejected over the basis that methacrylic acid polymer begins to dissolve around a pH of 6-7 and that zein begins to dissolve at a pH of above 9. It is further noted that the phrase "begins to dissolve" is relative, in that, any enteric polymer will "begin" to dissolve when contacted with a solution at any pH value.

16. In regards to claims 23-26: Changing the percentages as well as the ratios of components in pharmaceutical compositions is common in the art and is simply see as routine optimization in the art.

17. In regards to claim 27: Sackler teaches a sustained release oral pharmaceutical (see claim 17 above) consisting of:

(a) see claim 17 above

(i) oxycodone (col. 7, lines 31-34);

(ii) see claim 17 above

(iii) see claim 17 above

(iv) a lubricant (col. 12, line 47)

(v) a glidant (col. 12, line 48)

(b) see claim 17 above

(i) see claim 17 above

(ii) a second enteric coating agent that is assumed to begin to dissolve at a pH of above 7 (col.13, lines18-21);

(iii) an inert processing aid (col. 8, lines 10-12);

(iv) see claim 17 above

(c) see claim 17 above

(i) oxycodone (col. 6, lines 25-27)

(d) optionally a cosmetic coating (col. 7, lines 63-67).

18. Sackler does not teach an immediate release drug layer comprising a binder. Saslawski does teach a binder found within the immediate release drug layer (col. 5, line 59-col. 6, line13). Saslawski directly relates to the art, in that it teaches a tablet for instant and prolonged release of one or more active substances. It would have been obvious at the time of the invention for one of ordinary skill in the art to combine Sackler and Saslawski to add a binder, which is common in the art, to an immediate release drug layer.

19. In regards to claim 28: It is assumed that the binders named in Saslawski have a viscosity of greater than 75,000 mPa. It is also noted that binders are common in the art and that all binders act as functional equivalents for this invention, it is also noted that any nominal change in viscosity properties of said binders should not change the scope of this invention and therefore it is sufficient to reject this claim based on the rejection of a binder in the broader sense.

20. In regards to claims 29-30: It is assumed that the first enteric coating and the second enteric coating agent elected by the Applicant meet the limitations of claims 29-30 and therefore claims 29-30 are rejected over the basis that methacrylic acid polymer begins to dissolve around a pH of 6-7 and that zein begins to dissolve at a pH of above 8. It is further noted that the phrase "begins to dissolve" is relative, in that, any enteric polymer will "begin" to dissolve when contacted with a solution at any pH value.

21. In regards to claims 31-33: Changing the percentages as well as the ratios of components in pharmaceutical compositions is common in the art and is simply see as routine optimization in the art.

Obviousness Double Patenting

22. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application

claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

23. Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/726,024. The scope of the cited claims substantially overlap and one is obvious over the other. Although the conflicting claims are not identical, they are not patentably distinct from each other. While the copending application claims a central nervous system stimulant and not an opioid analgesic, this is immaterial because the other components that impart the controlled release properties represent the critical component. It would have been prima facie obvious to a person of ordinary skill in the art to substitute one drug for another in a sustained release formulation, because drug release would be expected to be a consequence of the formulations other components, irregardless of the drug used. The fact that two different kinds of known drugs are disclosed does not make either invention non-obvious. The

copending application also claims a binder and a diluent, while claim 1 in the instant application does not claim these two components specifically it does claim 1 or more excipients, which binders and diluents are. Further, in the instant application in claim 5 the excipients are identified as a binder and a diluent. The instant application claims a first and second enteric coating agent, while the copending application claims at least one enteric polymer, which reads on the instantly claimed invention, further, the copending application specifically claims methacrylic acid copolymer and zein as the enteric coating polymers in claim 11. Likewise the anti-sticking agent of the copending application and the inert processing aid of the instant application also read on each other.

Claims 2 and 3 of the instant application are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/726,024 for the same reasoning in regard to the core drug as above.

Claims 4 and 5 of the instant application are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/726,024 for the same reasoning as above regarding excipients including binders and diluents.

Claim 7 of the instant application is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/726,024 because several of the binder examples in claim 6 of the copending application are osmopolymers.

Claims 8 and 9 of the instant application are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/726,024 because it is assumed that the binders recited in claim 6 of the copending application also have the disclosed properties.

Claims 10-12 of the instant application are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/726,024 because it is assumed that the enteric polymers in the copending application also have the disclosed properties.

Claims 13-16 of the instant application are provisionally rejected on the ground of nonstatutory obviousness-type double patenting, as being unpatentable over claim 1 of copending Application No. 10/726,024 because the only limitation they add is that of different ratios and percentages of components, which is seen as routine optimization.

Claims 17-26 of the instant application are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/726,024 for the reasons given above. The claims recite the same components as above simply in a different format.

Claim 27 of the instant application is also provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable

over claim 1 of copending Application No. 10/726,024 in view of US Patent No. 6,485,746 to Campbell. The copending application does not specifically teach the core comprising a lubricant and a glidant. Campbell teaches that using many different excipients in drug manufacture is common and that using glidants as well as lubricants are standard in the art (col. 9, lines 14-31). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to add a glidant and a lubricant to the invention.

Claims 28-33 of the instant application are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/726,024 in view of US Patent No. 6,485,746 to Campbell. These claims are rejected because the only limitation they add is that of properties that the disclosed components are assumed to have, or different ratios and percentages of components, which is seen as routine optimization.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Luke E. Karpinski whose telephone number is

571-270-3501. The examiner can normally be reached on Monday Thursday 9-4 est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, Ardin H. Marschel or Cecilia Tsang can be reached on 571-272-0718 or 571-272-0562 respectively. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LEK

Cecilia J. Tsang
Supervisory Patent Examiner
Technology Center 1600